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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,726	11/19/2001	Avi J. Ashkenazi	P2730P1C60	9979

35489 7590 09/17/2004

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,726

Applicant(s)

GENENTECH, INC.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-126, 129-131 and 135-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 124-126, 129-131 and 135-138 is/are allowed.
- 6) ☒ Claim(s) 119-123 and 139-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/7/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 6/7/04 has been entered into the record.
- B. Claims 119-138 were pending in this Office Action. In the Amendment dated 6/7/04, Applicants canceled claims 127, 128 and 132-134 and added new claims 139-142. Therefore, claims 119-126, 129-131 and 135-142 are pending and are the subject of this Office Action.
- C. The Information Disclosure Statement dated 6/7/04 has been entered into the record. All references have been considered.
- D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority

- A. After review of Applicants' arguments as well as the specification, the Examiner agrees that gene amplification in colon tumors is a specific, substantial and well-established utility. Therefore, the present invention possesses utility under 35 USC 101 and is enabled under 35 USC 112, first paragraph. Therefore, the present invention receives priority to Provisional U.S. Application 60/141,037, filed June 23, 1999.

3. Specification

- A. Though no objection was made to the specification regarding hyperlinks, it is noted that Applicants have amended the specification to remove any hyperlinks.
- B. The objection to the specification regarding the title has been withdrawn in view of Applicants' amendment to the title to recite "Nucleic Acids Encoding PRO1281 Polypeptides."

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4. Claim Objections

A. The objection to claims 119-126, 129-131 and 135-138 has been withdrawn in view of Applicants' amendment to the claims to replace the phrase "shown in Figure 232 (SEQ ID NO:325)" with "of SEQ ID NO:325" and "shown in Figure 233 (SEQ ID NO:326)" with "of SEQ ID NO:326."

B. Claims 140-142 are objected to since the syntax could be improved by replacing the term "above" with "greater."

5. Claim Rejections - 35 USC § 101

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 101 has been withdrawn in view of Applicants' arguments that gene amplification in colon tumors is a specific, substantial and well-established utility.

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that the present invention is enabled since it has a specific, substantial and well-established utility under 35 USC 101.

B. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendment to the specification incorporating the requisite assurances that "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the pertinent U.S. patent." (also see original page 566 of the specification). Therefore, all requirements for the Deposit of Biological Materials have been met.

C. Claims 119-123 remain rejected and new claims 139-142 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 3/9/04. Applicants argue that the instantly pending claims have been amended to include a functional recitation "wherein said nucleic acid is amplified in colon tumors" and that they have removed references to "extracellular domains."

These arguments have been considered, but are not deemed persuasive. Page 5 of the Office Action mailed 5/6/04 states that "there are no working examples of polynucleotides or polypeptides less

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than 100% identical to SEQ ID NO:325 or 326.” Though Applicants have added a functional limitation, the claims are still broad because Applicants have only enabled the use of the polynucleotide of SEQ ID NO:325 (encoded by ATCC No. 203129) as being amplified in colon tumors. The only disclosure regarding PRO1281 (SEQ ID NO:325) can be found on pages 209, 362 and 554 (Table 9C) of the specification. Nowhere in the specification do Applicants disclose working examples of polynucleotides which are less than the full-length of SEQ ID NO:325, including those encoding SEQ ID NO:326, those which hybridize to SEQ ID NO:325, or to those encoding SEQ ID NO:326. Polynucleotides which are less than the full length of SEQ ID NO:325 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:325. Applicants have not provided any guidance as to what other polynucleotides are amplified in colon tumors other than that of SEQ ID NO:325, nor is it predictable to one of ordinary skill in the art which polynucleotides other than that of SEQ ID NO:325 would be amplified in colon tumors.

In summary, the breadth of the claims remains excessive with regard to Applicants claiming all polynucleotides which are less than the full length of SEQ ID NO:325 and which is amplified in colon tumors. There is also a lack of guidance and working examples of these polynucleotides other than that of SEQ ID NO:325. These factors, along with the lack of predictability to one of ordinary skill in the art as to which polynucleotides other than that of the full length polynucleotide of SEQ ID NO:325 would be amplified in colon tumors, leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

D. No rejection is being made over claim 137 even though it does not recite that the host cell is “isolated.” When read in light of the specification, these claims do not read on gene therapy. As defined in the specification “host cells are transfected or transformed with expression or cloning vectors described herein for PRO production *and cultured in conventional nutrient media* modified as appropriate for inducing promoters, selecting transformants, or amplifying the genes encoding the desired sequences” (emphasis added). The fact that these cells are cultured in conventional media demonstrates that these host cells are not transgenic.

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6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to include a functional limitation. However, new claims 139-142 are rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 3/9/04. Claims 139-142 recite the limitation that the nucleic acid is "suitable for use as a primer or probe." Applicants' arguments on pages 14-16 of the Response dated 6/7/04 appear to focus solely on the functional limitation that the polynucleotide is amplified in colon tumors. Therefore, these arguments have been considered, but are not deemed persuasive. No arguments regarding the functional limitation "primers or probes" have been provided. Regardless, further rationale for the rejection of claims 139-142 has been provided below.

These are genus claims. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The limitation "suitable for use as a primer or probe" is not a distinguishing attribute. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the nucleic acid class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, molecules which hybridize to the polynucleotides encoding these SEQ ID NOs and which are suitable as probes or primers (which could be at least thousands of molecules) alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made. It is believed that all pertinent arguments have been addressed.

7. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 139-142 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 139 recites hybridization conditions not found in the specification as originally filed (see Example 5 on pages 110-

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111). Furthermore the use of PCR probes or primers of the lengths recited in claims 139-142 could also not be found. Applicants are required to point out exactly where in the specification support for these new claims can be found. **This is a new matter rejection.**

8. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to delete reference to the "extracellular domain."

B. The rejection of claims 132-134 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' cancellation of these claims and the fact that newly added claims 139-142 recite exact hybridization conditions.

C. Claims 139-142 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 139 is confusing since it recites the nucleic acid of SEQ ID NO:326, However, SEQ ID NO:326 is a polypeptide. Claims 140-142 are rejected since they depend from claim 139.

9. Claim Rejections - 35 USC § 102

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 102(b) as being anticipated by Baker et al. has been withdrawn in view of Applicants' arguments that Applicants have made a proper assertion of priority based on U.S. Provisional Application 60/141,037 filed June 23, 1999. This date is prior to the international filing date of Baker et al.

10. Conclusion

A. Claims 124-126, 129-131, 135-138 are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 14, 2004


ROBERT LANDSMAN
PATENT EXAMINER